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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/725,049 | 12/01/2003 | Erming Xia | P03373 | 2954 |
| 23702 | 7590 | 07/24/2006 | EXAMINER | |
| Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701 | | | CHORBAJI, MONZER R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1744 | |

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,049

Applicant(s)

XIA ET AL.

Examiner

MONZER R. CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

This final is in response to the amendment received on 05/15/2006

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5-6 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al (U.S.P.N. 4,436,730).

Regarding claim 1, Ellis discloses an aqueous ophthalmic solution (col.1, lines 61-67 and col.5, lines 9-15) that includes quarternized ammonium cationic polysaccharides (col.10, lines 26-41 and examples VI-VII) in an amount effective for solution preservation (example VI and col.2, lines 54-62). Both the disclosure and Ellis use the same compound, which is quarternized ammonium cationic polysaccharide. The disclosure teaches that the compound quarternized ammonium cationic polysaccharide acts as a preserving agent. Therefore, Ellis compound necessarily acts as a solution preservative. See MPEP 2112. Specifically, see MPEP 2112.01.

Regarding claims 3 and 6, Ellis employs variations of polyquaternium 10 (example IV).

Regarding claims 5 and 13-15, Ellis discloses a method where cationic polysaccharides (example IV) is combined in amount effective (examples V-VII) for solution preservation (col.2, lines 54-62) where surfaces of contact lenses (i.e., medical

items) are treated over a time interval so that microbial burden (col.2, lines 59-62 and col.7, lines 59-61) on contact lenses is eliminated.

Regarding claims 9-12, Ellis teaches the following: the use of a buffer (col.7, lines 57-59), the use of tonicity agents (Example V), the use of surfactants (col.7, lines 56-57) and the use of viscosity agents (col.7, lines 49-50).

Response to Arguments

3. Applicant's arguments filed on 05/15/2006 have been fully considered but they are not persuasive.

On page 4 of the Remarks section, applicant argues that, "Ellis did not recognize that the quarternized ammonium cationic polysaccharides could be used in an ophthalmic composition to preserve the ophthalmic compositions". The examiner disagrees. See MPEP 2112. Specifically, see MPEP 2112.01.

On page 4 of the Remarks section, applicant argues that, "Accordingly, in each instance Ellis used an additional preservative in an amount effective to, at a minimum, preserve the solution." The examiner disagrees, since Ellis teaches that the use of preserving agent is optional and not basic and required part of the composition (col.2, lines 59-62 and col.7, lines 44-49) that if desired, it can be included in the composition. In some of the illustrated embodiments, Ellis has optionally included additional preserving agents so that synergistic effects of such agents result in increasing the strength of preservation.

On bottom of page 4 to page 5 of the Remarks section, applicant argues that the use of the transitional phrase "consisting essentially of" would exclude the presence of

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traditional preservative such as thiomersol or benzalkonium chloride. The examiner disagrees with the characterization of such a phrase. The phrase would only exclude components that interfere with the characteristic of the claimed composition. Ellis teaches that traditional preserving agents can be optionally added to a composition containing quarternized ammonium cationic polysaccharides. This means that the characteristics of the composition are maintained upon mixing of quarternized ammonium cationic polysaccharides with traditional preserving agents. In addition, Ellis recognizes that the solution must be compatible with the eye and should be non-irritating (col.2, lines 30-35). Furthermore, Ellis teaches that the solution can be directly applied to the eye (col.15, lines 67-68 and col.16, lines 1-2). Clearly, Ellis solution is beneficial and comfortable to the eye of a patient.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monzer R. Chorbaji
07/14/2006


GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER